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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/466,554	06/06/1995	PETER A. SEUBERT	15270-002120	3168

20350 7590 05/23/2007
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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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05/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/466,554	SEUBERT ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-31-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-45, 48 and 51-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-45, 48 and 51-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2005</u> . | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The response and amendment filed 10-31-05 has been entered into the record. Claims 42-45, 48 and 51-54 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 45 and 46 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment to the claims.

The rejection of claims 48 and 51-54 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

The rejection of claims 43-46 and 48 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

Rejections Maintained

Double Patenting

Claims 42-45, 48 and 51-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all the allowed claims of U.S. Patent No. 6,284,221 in view of Viego Pelfrey et al (of Record) and Suzuki et al for reasons made of record in the Office Action mailed 8-16-04 .

Applicants' arguments have been carefully considered but are not persuasive. Applicants argues the diagnostic method of the '221 patent. This is not persuasive, the rejection of record in an obvious double patenting rejection and the patented claims are

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not drawn to a diagnostic but to a screen for soluble amyloid beta production inhibitors. Applicants arguments drawn to non-obviousness issues of the diagnostic method are therefore not on point and irrelevant to the double patenting rejection. The claims are drawn to screening for the ability to alter the amount of an amyloid beta ($x \geq 41$) in a CSF sample. The patent is drawn to screening for soluble amyloid beta production inhibitors (i.e. the instantly claimed altering the amount) in CSF (see Patented claim 5). Further, the Patented claims indicate that the soluble amyloid beta peptide is measured and the intact amyloid beta or a fragments thereof. Viego-Pelfrey is cited to teach that amyloid beta ($x \geq 41$) is present in the CSF and is "soluble". As such, measurement of the instantly claimed soluble species in CSF using non-cross reactive antibodies of Suzuki et al is in fact obvious.

Claims 42-45, 48 and 51-54 directed to an invention not patentably distinct from claims 1-9 of commonly assigned Patent 6,284,221. Specifically, it would have been obvious to measure soluble amyloid beta ($x \geq 41$) production inhibitors because the art teaches soluble amyloid beta ($x \geq 41$) is found in the CSF of affected individuals and Suzuki et al teach how to measure such as set forth in the office action mailed 8-16-04.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 6,284,221, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

New Objections/Rejections

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: the specification does not specifically state the relationship between the applications (07/965,972; 08/079,511). Further, neither of these applications can provide written description support the now claimed subject matter.

Claim 48 is objected to because of the following informalities: the phrase "the antibody of fragment thereof binds to" should read "the antibody or fragment thereof binds to". Appropriate correction is required.

Claims 42-45, 48 and 51-54 are rejected under 35 U.S.C. 103(a) as being obvious over Schenk et al, U.S. Patent No. 6,284,221 with priority to 07/911,647 filed July 10, 1992 in view of Viego Pelfrey et al (of Record) and Suzuki et al (of record).

Schenk et al teach all the limitations of the claimed method (see claims 1-9). Schenk et al teach the Sweedish mutation and animal models thereof (see column 10, lines 40- column 11, line 2). Schenk et al differs by not teaching soluble amyloid beta ($x \geq 41$).

Viego Pelfrey et al teach that there are soluble forms of amyloid beta ($(x \geq 41)$) and amyloid beta (1-42) are specifically present in the CSF.

Suzuki et al teach a sandwich enzyme linked immunosorbent assay which measures amyloid beta (1-42) in a fluid sample using the combination of the monoclonal antibody

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BAN50, which specifically binds A β (1-16) and the monoclonal antibody BC-05 which was raised to amyloid beta (33-43) (see pages 1337-1338). Suzuki et al teach that the assay was specific for amyloid beta (1-42) and does not detect amyloid beta (1-40) and thus innately measures amyloid beta ($x \geq 41$; ($x \geq 42$) and ($x \geq 43$)).

It would have been *prima facie* obvious to one of ordinary skill in the art to modify the assay of the '221 patent by measuring the species of soluble amyloid beta ($x \geq 41$) by means of the assay of Suzuki et al because Viego-Pelfrey et al teach that amyloid beta (1-42) is a soluble species of amyloid beta present in cerebrospinal fluid samples of affected individuals.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Status of the Claims

All claims stand rejected.

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Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Patricia A. Duffy

Primary Examiner

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